IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION 600 Pennsylvania Avenue, NW Washington, D.C. 20580 Plaintiff, v. CEPHALON, INC. 41 Moores Road Frazer, Pennsylvania 19355 Defendant.	Civil Action No. 08-cv-2141-MSG

PLAINTIFF FEDERAL TRADE COMMISSION'S MEMORANDUM IN OPPOSITION TO DEFENDANT CEPHALON'S MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

Federal Regulations

Federal Statutes

Federal Legislative Materials

Federal Administrative Materials

Other Authorities

INTRODUCTION

The FTC's complaint tells a straightforward story of anticompetitive conduct. By late 2005, Cephalon faced imminent competitive threats from four rivals seeking to market generic versions of Cephalon's flagship product, a blockbuster sleep disorder drug called Provigil. Generic entry was widely expected to occur in June 2006. When it did, consumers would reap enormous benefits. The generic firms planned to price their versions of Provigil at a fraction of Cephalon's price, saving consumers hundreds of millions of dollars a year.

But for Cephalon, generic competition to Provigil would be devastating. Provigil revenues accounted for nearly half of Cephalon's total business. Generic competition would cause these revenues to plummet. While Cephalon had lodged patent infringement claims against the four generic companies, it did not expect its narrow patent to prevent generic entry. Indeed, Cephalon had warned investors that Provigil would be "going away" in 2006.

Aware that generic entry was imminent and that its patent was unlikely to prevent it, Cephalon decided to use its monopoly profits to buy the protection from competition that its patent would not afford. In less than two months, it negotiated settlement deals with all four potential rivals to stay out of the market until 2012. To secure these agreements, Cephalon paid the generic companies over $200 million in total. As a result, in the words of Cephalon's CEO, "We were able to get six more years of patent protection. That's $4 billion in sales that no one expected."

Cephalon's lucrative scheme, however, has forced American consumers to pay a steep price. Without the generic competition that would otherwise have existed, consumers continue to pay Cephalon's monopoly price. In fact, for every day that they are denied the opportunity to purchase generic Provigil, consumers pay roughly $2 million more for the branded product. And

the cost to consumers continues to rise. Today, consumers pay even more than they did when the FTC brought these charges, because Cephalon repeatedly raises the price of Provigil – 28 percent in 2008 alone. Moreover, as a result of Cephalon's conduct, consumers may never enjoy the benefits from generic competition to Provigil: Cephalon's price increases are only part of its deliberate campaign to eliminate the market for generic Provigil in advance of generic entry in 2012 by switching consumers to a follow-on product, Nuvigil. Cephalon's CEO has publicly boasted: "[I]f we do our job right [switching the market to Nuvigil] . . . the Provigil number in 2012 that will be genericized will be very, very small."

Cephalon's course of conduct to eliminate threats to its Provigil monopoly by sharing its monopoly profits is unlawful. This elimination of competition flows not from the protection afforded by Cephalon's patent, but rather from the illegal sharing of its monopoly profits with would-be rivals. Cephalon's monopoly is preserved by the "preference of the competitors for a mutual arrangement," one that "promises more profit if the parties abandon rather than maintain competition." *United States v. Masonite Corp.*, 316 U.S. 265, 281 (1942). The FTC amply alleges facts that demonstrate this anticompetitive arrangement: generic firms planned to enter in 2006; Cephalon expected this entry to occur but did not expect its patent to prevent it; Cephalon paid each of the generics to delay their entry until 2012; and delaying such entry causes significant harm to consumers. For purposes of this motion, these facts must be accepted as true.

But according to Cephalon, none of these facts matter. The mere possession of a patent, it contends, conveys the inexorable right to exclude any challenger until patent expiration – a right that may be exercised by splitting monopoly profits with potential entrants to induce them to abandon their patent challenges and refrain from competing. In Cephalon's view, the patent

holder's right to purchase protection from competition is not tempered by the strength of its patent, so long as the infringement claim is not a sham. Def.'s Mem 2. Indeed, under Cephalon's end-of-patent-term standard (what it calls the "scope of the patent test"), courts must disregard complaint allegations that the patent was either invalid or so narrow that it would not prevent generic entry on its own. Nor does it matter that patent holders are most likely to use exclusion payments to protect the weakest patents. Thus, under Cephalon's standard, even a trivial patent would give the patent holder the right to use monopoly profits to buy protection from competition until patent expiration. This contention – that an untested patent grants a monopolist a virtually absolute right to exclude through sharing monopoly profits – is the sole basis for Cephalon's motion to dismiss the FTC's monopolization charge.

The only issue, therefore, is whether to adopt this extreme view. This Court should not do so. The end-of-patent-term standard misconstrues the nature of patent rights and inappropriately diminishes fundamental antitrust principles. Because of the threat to competition from patent settlements that include payments from branded drug patent holders to would-be generic rivals, the Department of Justice considers such settlements to be "presumptively unlawful," that is, illegal absent adequate justification.[1] The FTC has advocated a similar approach. There are a variety of practical ways for the antitrust analysis of such settlements to account for Cephalon's patent, but the end-of-patent-term standard improperly treats a patent as a blank check to purchase protection from generic competition. Under this standard, such conduct is *conclusively lawful* (absent proof of fraud or sham litigation). By effectively barring

[1] Brief for the United States in Response to the Court's Invitation, at 21, *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, Nos. 05-2851, 05-2852, 05-2863 (2d Cir.), filed July 6, 2009, *available at* <http://www.usdoj.gov/atr/cases/f247700/247708.pdf> ("DOJ *Cipro* Amicus Br.").

consideration of whether such an agreement might violate the antitrust laws, this standard is inconsistent with the public interest in avoiding unwarranted patent monopolies and the Supreme Court's antitrust and patent jurisprudence. For these reasons, Cephalon's motion to dismiss should be denied.

BACKGROUND

The Hatch-Waxman Act

Congress passed the Hatch-Waxman Act to make available more low-cost generic drugs, while maintaining incentives for innovation by fully protecting legitimate patent claims.[2] The Act allows for accelerated FDA approval of a generic drug through an Abbreviated New Drug Application (ANDA), upon a showing, among other things, that the new drug is "bioequivalent" to an approved branded drug. 21 U.S.C. § 355(j)(2)(A).

The Hatch-Waxman Act reflects a congressional judgment that weak patents should not create unwarranted barriers to competition from generic drugs. It establishes certain rights and procedures that apply when a company seeks FDA approval to market a generic product before expiration of a patent relating to the counterpart brand-name drug. In such cases, the generic applicant must: (1) certify to the FDA that the patent in question is invalid or not infringed by the generic product (known as a "Paragraph IV certification"); and (2) notify the patent holder of the filing of the certification. If the patent holder files suit within 45 days, FDA approval to market the generic drug is automatically stayed for 30 months, unless before that time the patent expires or is judicially determined to be invalid or not infringed. 21 U.S.C. § 355(j)(2). To encourage generic drug companies to challenge weak patents, the Hatch-Waxman Act awards

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[2] *See, e.g., SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 690 (E.D. Pa. 2004).

the first generic companies to file an ANDA containing a Paragraph IV certification 180 days of marketing exclusivity, during which the FDA may not approve a potential competitor's ANDA. 21 U.S.C. § 355(j)(5)(B)(iv). As a result, a later ANDA filer cannot obtain FDA approval to enter the market until 180 days after the first filer begins selling its product, unless the first filer relinquishes or forfeits its exclusivity claim. As the facts of this case reflect, multiple generic applicants may share the claim to the 180-day exclusivity period. (*See* FAC ¶ 38.)

Competition Under the Hatch Waxman Act

This congressional framework to encourage generic firms to challenge weak patents has resulted in enormous benefits to consumers. Generic competitors typically enter the market at a steep discount to the brand price, and branded drugs consequently see a dramatic and immediate erosion of sales. (FAC ¶¶ 19, 22.) Apotex's challenge to patents on the branded anti-depression drug Paxil provides a compelling example. In March 2003, a district court ruled that Apotex did not infringe one of these patents.[3] Apotex launched its generic version of Paxil in September 2003 "at risk" – that is, while the district court ruling was on appeal and while other patent challenges were pending in this district (concerning patents expiring as late as 2015). In April 2005, the Federal Circuit affirmed the judgment in favor of Apotex.[4] Early "at-risk" entry of generic Paxil saved consumers billions of dollars.

Although patent challenges have the potential for substantial consumer savings, the competitive dynamic between brand-name drugs and their generic equivalents creates an

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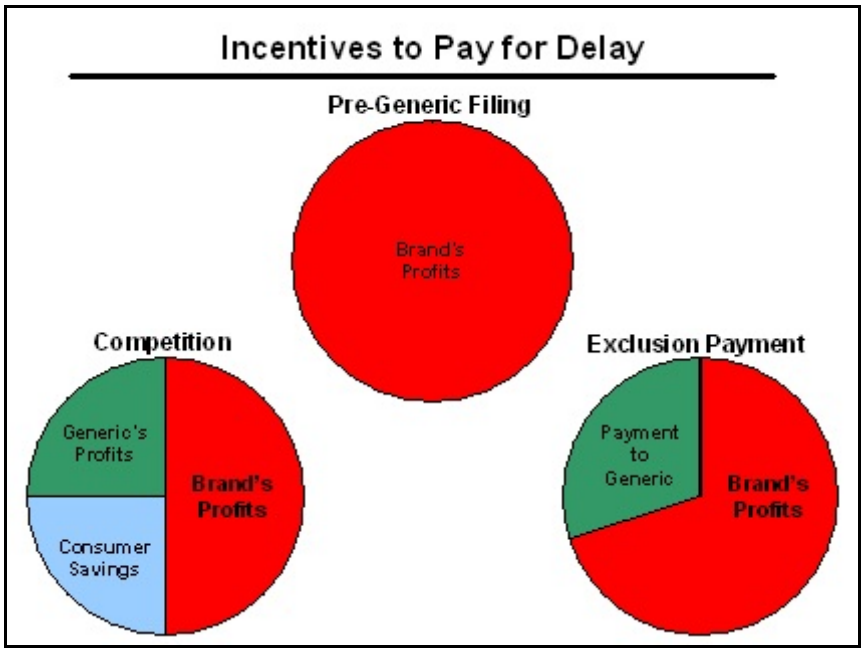
[3] *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011 (N.D. Ill. 2003).

[4] *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005) (aff'd on other grounds).

incentive for brand and generic manufacturers to conspire to avoid competition and share the resulting profits. The profits the generic expects to make will almost always be much less than the profits the brand stands to lose. Thus, it will be more profitable for both if the brand firm pays the generic to settle the patent dispute and agree to defer entry. (¶ 86.) Consumers, however, lose the possibility of earlier generic entry and the substantial savings that would result from price competition.



In recognition of the threat that such agreements pose and to promote effective antitrust enforcement, Congress amended the Hatch-Waxman Act in 2003 to require brand-name companies and generic applicants to file patent settlement agreements with the FTC and the Department of Justice.[5] As a Senate report explained, those amendments sought to stamp out the "abuse" of Hatch-Waxman law resulting from "pacts between big pharmaceutical firms and

[5] Pub. L. No. 108-173, Title XI, Subtitle B, 117 Stat. 2066, 2461 (contained in 21 U.S.C. § 355, historical notes).

makers of generic versions of brand name drugs, that are intended to keep lower cost drugs off the market."[6]

The Complaint Allegations

Provigil

Cephalon sells a prescription drug containing modafinil that it markets under the name Provigil. (FAC ¶ 26.) Provigil is considered to be the "gold standard" for treating excessive sleepiness in patients with certain sleep disorders. (¶ 29.) Provigil is by far Cephalon's largest-selling product, with U.S. sales exceeding $920 million in 2008. (¶¶ 30, 32.)

The active pharmaceutical ingredient in Provigil is modafinil. When the patent covering the modafinil compound expired in 2001, Cephalon's only unexpired patent relating to Provigil was a formulation patent that relates to the distribution of a specified size of particles of modafinil. (¶¶ 34-35.) Unlike the modafinil compound patent, Cephalon's particle size patent is narrow and does not block all generic competition to Provigil. (¶ 37.) A consultant advised Cephalon in 2002 that "all generic drug companies know" that infringement of the particle size patent may be "easily" avoided by manufacturing their products to contain a distribution of modafinil particle sizes different than that covered by Cephalon's patent. (¶ 37.)

The Threat of Generic Competition to Provigil

On December 24, 2002 – the first possible day the FDA could accept an ANDA for generic Provigil – four companies (hereinafter the "first filers") filed ANDAs that challenged Cephalon's particle size patent. (¶ 38.) Each certified to the FDA that its version of generic Provigil did not infringe Cephalon's patent, that the patent was invalid, or both. (¶ 38.) In

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[6] S. Rep. No. 107-167, at 4 (2002), *available at* <http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_reports&docid=f:sr167.pdf>.

March 2003, Cephalon filed a patent infringement action against each of the first filers, triggering an automatic stay of final FDA approval of the generic Provigil applications. (¶ 43.)

By late 2005, generic competition to Provigil appeared imminent to Cephalon, the generic firms, and Wall Street analysts who follow the industry. (¶ 50.) Each of the four first filers expected to receive final FDA approval of its version of generic Provigil when the applicable regulatory stays expired in June 2006. (¶ 49.) Upon receiving final approval, each generic could lawfully launch its product "at risk" unless Cephalon obtained a preliminary injunction.[7] (*Id.*) "Launching at risk" – that is, at risk of liability for damages if the patent holder ultimately prevails in its lawsuit – occurs with some frequency in the pharmaceutical industry. Indeed, one of the first filers has launched "at risk" more than 20 times. (*Id.*)

Cephalon expected an "at risk" generic Provigil launch when the regulatory stay expired in June 2006. In November 2005, Cephalon told investors that Provigil was "going away" because of generic entry in 2006. (¶ 50). Cephalon knew that when generic entry did occur, its branded Provigil sales would plummet. (¶ 41.) Meanwhile, Cephalon had planned to blunt the impact of generic Provigil competition by introducing a successor product called Nuvigil – but that plan was in jeopardy because the FDA still had not approved Nuvigil as of late 2005. (¶ 54.)

Cephalon's Anticompetitive Scheme

Rather than test the strength of its patent by seeking a preliminary injunction to block "at risk" generic entry, Cephalon set out to protect its Provigil monopoly by settling its patent litigation with the four first filers under terms that would eliminate potential generic competition

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[7] *See, e.g., Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 684 (Fed. Cir. 1990) (alleged infringer has legitimate right to compete where patentee fails to show likelihood of success in proving infringement).

for six years. (¶¶ 56, 97.) The first filers, however, were unwilling to accept significantly deferred entry absent compensation from Cephalon. (¶ 57.) To achieve the exclusion it sought, Cephalon entered a series of settlement agreements under which it paid each generic company – more than $200 million collectively – to abandon its patent challenge and forgo entry until April 2012. (¶¶ 3, 58-78.) Having successfully settled with the four first filers, Cephalon then took further steps to ensure that generic entry would not occur prior to April 2012. (¶¶ 87-91.)

Cephalon is now engaged in a deliberate campaign to eliminate the market for generic Provigil by the time generic products could enter in 2012. In June 2009, Cephalon launched Nuvigil. Cephalon's CEO has boasted that Cephalon's success in switching consumers to Nuvigil will dramatically decrease patients' opportunity to purchase generic Provigil in the future: "[I]f we do our job right [switching the market to Nuvigil] . . . the Provigil number in 2012 that will be genericized will be very, very small." (¶ 93.)

The Effects of Cephalon's Conduct

By sharing its monopoly profits with the first filers to secure their agreement to defer entry until 2012, Cephalon eliminated the most direct and immediate threat to its monopoly. Absent the compensation Cephalon agreed to provide, generic competition to Provigil would have occurred prior to April 2012 because: (1) one or more of the first filers would have marketed its version of generic Provigil "at-risk" before the patent litigation concluded; (2) Cephalon would not have prevailed against each of the four first filers in the litigation; or (3) Cephalon would have agreed to settle the litigation on terms that did not compensate the first filers, but instead provided for generic entry earlier than April 2012. (¶ 85.)

In addition, the cumulative effect of the four settlements has been to create a barrier – the first filers' 180-day exclusivity period – to all other potential generic Provigil competitors,

regardless of whether their products would infringe Cephalon's patent. (¶¶ 87-91.) Thus, Cephalon may succeed in excluding all potential generic competition to Provigil until April 2012, nearly six years after generic entry was likely to occur. Even then, consumers may realize few benefits from the entry of generic Provigil because of Cephalon's ongoing efforts to switch sales from Provigil to Nuvigil.[8] (¶ 93.)

ARGUMENT

A motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure may be granted only if the movant demonstrates that, after accepting the factual allegations in the complaint as true and drawing all reasonable inferences in the non-moving party's favor, the complaint fails to state a claim upon which relief can be granted. *See, e.g., Phillips v. County of Allegheny*, 515 F.3d 224, 231-33 (3d Cir. 2008). At this stage, the appropriate question is "not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 563 n.8 (2007) (citation omitted). In evaluating a Rule 12(b)(6) motion, the Court may consider the facts alleged in the pleadings, documents attached to or referred to in the complaint, and matters properly subject to judicial notice. *See, e.g., Southern Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Group Ltd.*, 181 F.3d 410, 425-27 (3d Cir. 1999).

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[8] In its motion, Cephalon incorrectly asserts that permitting the first filers to launch their products three years prior to patent expiration is "obviously pro-competitive." (Def.'s Mem. 1.) In any event, at this stage, the Court must accept the FTC's allegation that generic entry in 2012 will likely provide few benefits to consumers because of Cephalon's ongoing switch strategy. (FAC ¶¶ 54, 93.) *See, e.g.*, *Mitel Corp. v. A&A Connections, Inc.*, No. 97-4205, 1998 WL 136529, at *4 (E.D. Pa. Mar. 20, 1998) (rejecting, on motion to dismiss, antitrust defendant's assertion that exclusive distribution network was procompetitive).

I. The Complaint States a Valid Claim of Monopolization

The offense of monopolization has two basic elements: "(1) the possession of monopoly power in the relevant market, and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966). "Unlawful maintenance of a monopoly is demonstrated by proof that a defendant has engaged in anticompetitive conduct that reasonably appears to be a significant contribution to maintaining monopoly power." *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005).

The Third Circuit has observed that "[a]nticompetitive conduct can come in too many different forms, and is too dependent upon context, for any court or commentator to have enumerated all the varieties." *LePage's Inc., v. 3M*, 324 F.3d 141, 152 (3d Cir. 2003) (internal citations omitted). Indeed, the Third Circuit has found that a broad range of conduct can be unlawfully exclusionary. *See Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297 (3d Cir. 2007) (patent holder engaging in deceptive conduct before standard-setting organization); *Dentsply*, 399 F.3d at 181 (exclusive contracts denying access to a particular distribution channel); *LePage's*, 324 F.3d at 141 (exclusive dealing and bundled rebates); *Mannington Mills, Inc. v. Congoleum Indus., Inc.*, 610 F.2d 1059 (3d Cir. 1979) (patent licensing practices); *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056 (3d Cir. 1978) (bundling of pharmaceutical products). Where the complaint alleges various exclusionary acts, the court must evaluate the "monopolist's conduct taken as whole rather than considering each aspect in isolation." *LePage's*, 324 F.3d at 162 (citing *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 698-99 (1962)); *see also Abbott Labs. v. Teva Pharms., USA, Inc.*, 432 F. Supp. 2d 408,

430-31 (D. Del. 2006) (Jordan, J.) (applying same principle and denying motion to dismiss antitrust counterclaims challenging scheme to thwart generic competition).

The FTC's complaint alleges that Cephalon has a monopoly with respect to Provigil sales in the United States and that it has unlawfully maintained its monopoly through a course of anticompetitive conduct to prevent entry of lower-cost generic competition. The complaint includes numerous allegations that, if proven, would permit the Court to conclude that Cephalon's course of conduct was unlawfully exclusionary, including: the terms Cephalon used to induce the first filers to delay their entry for six years (FAC ¶¶ 57-60, 62-78); the circumstances that made it so important for Cephalon to buy settlements with all of the first filers before the regulatory stay expired in June 2006 (¶¶ 1, 2, 19-22, 30-33, 41-42, 47-50, 54-55); the widely-held view that it was easy for generics to avoid infringing Cephalon's narrow formulation patent (¶¶ 37-38, 50-53); and the deliberate campaign by Cephalon to eliminate the market for generic Provigil by the time generic products could enter in 2012. (¶ 93).

Cephalon's motion to dismiss does not challenge the allegations that it possesses monopoly power. Nor does it dispute that, in the absence of its particle size patent, the complaint would allege cognizable acts of exclusionary conduct. The only issue therefore is whether the mere presence of that patent means that, as a matter of law, the alleged conduct cannot be exclusionary.

A. Paying a potential competitor to stay out of the market is presumptively anticompetitive

This case challenges an incumbent firm's sharing of its monopoly profits with four potential competitors to protect its monopoly product from competition until 2012. Paying a potential competitor to stay out of the market is a classic restraint of trade, and is presumptively

anticompetitive, because it directly restricts competition on price and output. *See Palmer v. BRG of Ga. Inc.*, 498 U.S. 46, 49-50 (1990) (per curium).[9] As the leading treatise on antitrust law observes, "the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." XII Herbert Hovenkamp, Antitrust Law ¶ 2030b at 213 (2005); *see also United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc) (monopolist's exclusionary conduct is unlawful when it "is aimed at producers of nascent competitive technologies as well as when it is aimed at producers of established substitutes"); *Engine Specialties, Inc. v. Bombardier Ltd.*, 605 F.2d 1 (1st Cir. 1979) (holding illegal a non-compete agreement between motorcycle manufacturer and potential entrant that agreed to be exclusive distributor for incumbent). Cephalon's sharing of its monopoly profits to induce its four generic rivals to abandon plans to compete directly limited price competition by thwarting imminent generic competition to Provigil, thus enabling Cephalon to maintain high prices without losing sales.

B. A patent holder's sharing of monopoly profits to exclude an alleged infringer is unlawful exclusionary conduct

The law grants certain rights and protections to patent holders. But it does not grant a patent holder the right to exclude alleged infringers by any means it chooses. Otherwise, a patent holder alleging infringement could simply engage in various acts of self-help to exclude an alleged infringer, such as seizing the accused product. The D.C. Circuit makes this point using a graphic analogy in the *Microsoft* case:

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[9] *See also NCAA v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 107-08 (1984) ("Restrictions on price and output are the paradigmatic examples of restraints of trade that the Sherman Act was intended to prohibit.")

> [Microsoft] claims an absolute and unfettered right to use its intellectual property as it wishes: "[I]f intellectual property rights have been lawfully acquired," it says, then "their subsequent exercise cannot give rise to antitrust liability." . . . That is no more correct than the proposition that use of one's personal property, such as a baseball bat, cannot give rise to tort liability.

253 F.3d at 63; *see also SmithKline Corp. v. Eli Lilly & Co.*, 427 F. Supp. 1089, 1121 (E.D. Pa. 1976) (the "grant of a United States patent on [one or more drug products] does not immunize a [branded firm] from the impact of the antitrust laws if it misuses its monopoly"), *aff'd*, 575 F.2d 1056 (3d Cir. 1978).

The Supreme Court's decision in *United States v. Masonite Corp.,* 316 U.S. 265 (1942) makes the same point in the context of patent litigation settlements. That decision held that a patent holder uses impermissible means to exclude would-be competitors when it shares monopoly profits to induce them to refrain from competing. *Id.* at 279. In *Masonite*, a patent owner sued or threatened to sue its potential competitors for patent infringement. To resolve these disputes, the patent owner licensed the competing firms to sell its product, but at a price that it set. In return, the alleged infringers abandoned their efforts to sell their own, competing product. Addressing these facts, the Supreme Court noted that a "patentee who employs such an agent to distribute his product certainly is not enlarging the scope of his patent privilege if it . . . operates only to secure to him the reward for his invention which Congress has provided." *Id.* But the Court held that a patent holder does more than secure a reward for its invention when it shares monopoly profits with potential competitors to entice them to abandon their own products and patent challenges:

> Active and vigorous competition then tend to be impaired, not from any preference of the public for the patented product, but from the preference of the competitors for a mutual arrangement for price-fixing which promises more profit if the parties abandon rather than maintain competition.

Id. at 281. There is no suggestion in *Masonite* that the patent owner restrained competition "beyond the life of the patent." (Def.'s Mem. 1.) Nonetheless, the Supreme Court found that the use of settlements to share monopoly profits with patent challengers to induce them to stay out of the market exceeded the patentee's legitimate patent rights, and violated the antitrust laws.[10]

This is the crux of the antitrust claim here.[11] As in *Masonite*, the complaint alleges that Cephalon sued its potential competitors for patent infringement, and then settled in a manner that exceeded Cephalon's legitimate patent rights. As in *Masonite*, Cephalon used business arrangements that were entered into in connection with these settlements to align the interests of would-be competitors with Cephalon's and share in the resulting monopoly profits. As in *Masonite*, by sharing profits with its potential rivals, Cephalon induced them to forgo their patent challenges and keep their own products off the market (here for a period of six years), without regard to the exclusionary force – or lack thereof – of Cephalon's patent. *See Masonite*, 316 U.S. at 281 (sharing monopoly profits is a "powerful inducement to abandon competition"). Thus, the restraint on generic competition flows not from the protection afforded by Cephalon's

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[10] *See also United States v. New Wrinkle Inc.*, 342 U.S. 371 (1952) (holding price-fixing agreement involving an unresolved patent dispute unlawful under the antitrust laws, even though patent holder might have secured a judgment excluding competition to the end of patent life).

[11] Cephalon tries to distinguish *Masonite* on the ground that it involves a price-fixing agreement. (Def.'s Mem. 31.) But agreements in which competitors share the benefits of not competing are anticompetitive whether they involve price fixing agreements (as in *Masonite*) or payments not to compete (as alleged here). *See Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic*, 65 F.3d 1406, 1415 (7th Cir. 1995) ("It would be a strange interpretation of antitrust law that forbade competitors to agree on what price to charge, thus eliminating price competition among them, but allowed them to divide markets, thus eliminating all competition among them."); *Gen. Leaseways, Inc. v. Nat'l Truck Leasing Ass'n*, 744 F.2d 588, 594-95 (7th Cir. 1984) ("raising price, reducing output, and dividing markets have the same anticompetitive effects").

patent but rather from the "preference of the competitors for a mutual arrangement," one that "promises more profit if the parties abandon rather than maintain competition." *Id.*[12]

The Sixth Circuit in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003), similarly observed that the means a patent holder uses to exclude alleged infringers can give rise to antitrust liability. In condemning an agreement in which a branded drug firm paid its potential generic rival to stay out of the market during the pendency of patent litigation, the court rejected the same suggestion Cephalon advances here: that in paying its potential competitor to achieve the exclusion, the patent holder was merely "attempt[ing] to enforce patent rights":

> [I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market.

332 F.3d at 908; *see also Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (on a motion to dismiss, it was reasonable to infer that payments to an allegedly infringing generic rival were to obtain protection that the patent did not provide); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1317 (S.D. Fla. 2005) (on summary judgment, holding exclusion payments to allegedly infringing generic illegal because defendants through payments "agreed to extend the protections of the patent"). Indeed, the Department of Justice recently told the Second Circuit that it should be "presumptively unlawful" for a branded drug patent holder to purchase protection from competition from generic patent challengers:

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[12] Cephalon claims that its end-of-the-patent term standard "derives directly" from Supreme Court precedent, quoting language from the Supreme Court's decisions in *Masonite*, 316 U.S. at 265, *United States v. Line Material Co.*, 333 U.S. at 287, and *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963), to the effect that a patent holder may not extend its monopoly beyond the limits of what has been granted. (Def.'s Mem 12.) But assertion of this principle simply begs the question – whether sharing monopoly profits to achieve exclusion falls *within* the exclusionary rights granted. Indeed, as discussed above, *Masonite* says it does not.

"Absent another explanation for it, such a payment is naturally viewed as consideration for the generic's agreement to delay entry beyond the point that would otherwise reflect the parties' shared view of the likelihood that the patentee would ultimately prevail in the litigation."[13]

The only court in this Circuit to consider similar allegations declined to dismiss the antitrust complaint. In *In re K-Dur Antitrust Litigation*, 338 F. Supp. 2d 517, 531 (D.N.J. 2004), the defendants argued, as Cephalon does, that "[the brand company] had a valid patent, and thus was entitled to exclude generic competitors from the market until the patent expired." Acknowledging that defendants' argument had "a certain logical appeal," Judge Greenaway concluded on closer examination that, notwithstanding the presence of the patent, the use of payments to induce generic firms to abandon their patent challengers "obvious[ly]" can be anticompetitive by distorting the generic's incentive to compete:

> The patent regulatory regime creates incentives for generic manufacturers to challenge patents. . . . It would appear obvious that this incentive system can be distorted by cash payments made by a branded patent holder to generic manufacturers to discontinue patent validity or infringement challenges.

Id. at 531. Although Cephalon tries to dismiss Judge Greenaway's decision pointing on a special master's pending recommendation to grant summary judgment for defendants in *K-Dur*, the special master's report has no precedential value. *See In re K-Dur Antitrust Litig.*, No-01-1652, 2009 WL 508869 (D.N.J. Feb. 6, 2009). It is simply a recommendation, one which the district court is free to reject.[14]

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[13] DOJ *Cipro* Amicus Br., *supra* note 1, at 10, 22.

[14] The district court cases from the Third Circuit that Cephalon relies on (*see* Def.'s Mem. 12 n.10) do not support the end-of patent-term standard. While both looked at whether conduct was within the rights granted by the patent, that again simply begs the question whether patent rights encompass the sharing of monopoly profits to purchase protection from competition that the patent would not provide. Neither case address that question. Indeed, neither case even

In sum, the FTC's complaint alleges that Cephalon's exclusionary conduct stems not from the mere act of settling or from granting consideration in settlement, but rather its use of a particular form of consideration – a share of its monopoly profits – to achieve an exclusion that Cephalon's patent alone could not provide.[15]

II. The End-of-Patent-Term Standard Is Contrary to Supreme Court Authority and Based on Flawed Premises

Cephalon challenges the legal basis for the FTC's monopolization claims based primarily on decisions outside this jurisdiction, rather than Supreme Court and Third Circuit jurisprudence. To be sure, *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006), and *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008) accept Cephalon's extreme view of patent rights – that, absent a sham allegation, the existence of a patent entitles the owner to purchase the equivalent of a permanent injunction until patent expiration. But, as discussed below, this end-of-patent-term standard grants more protection than patent law provides. It disrupts the careful balance embodied in the patent system by overprotecting weak and narrow patents; it inappropriately equates a patentee's unilateral "right

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involved horizontal competitors. *See Sheet Metal Duct Inc. v. Lindlab, Inc.*, No. 99-6299, WL 987865 (E.D. Pa. July 18, 2000) (exclusive distribution arrangement between manufacturer and distributor); *United States v. CIBA Geigy Corp.*, 508 F. Supp. 1118 (D.N.J. 1976) (agreement between patentee and manufacturing licensee).

[15] Cephalon is wrong that an exclusion payment settlement is no different than any other type of settlement, which necessarily includes some consideration. (Def.'s Mem. 16 n.11 (citing *dicta* in *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003))). While all settlements include some form of consideration flowing between the parties, the type of consideration matters in antitrust analysis. Some types of consideration, such as an early entry date, a royalty to the patent-holder, or a compromise on a damage claim, do not generally involve sharing the benefits that come from eliminating potential competition. But if the consideration amounts to a sharing of profits achieved by avoiding competition, then that conduct is at the core of what the antitrust laws proscribe.

to exclude" through litigation with a right to settle litigation by sharing monopoly profits with a potential competitor; and it is premised on flawed factual assertions that are at odds with the FTC's complaint and with the reasoning applied by the Third Circuit in antitrust cases.

A. The end-of-patent-term standard is inconsistent with the Supreme Court's view of patent rights

It has long been clear that a patent is not an iron-clad right to exclude.[16] When a patent holder seeks to enforce its patent against an alleged infringer, it has the burden of proving that the challenged product falls within the scope of a patent's claims as properly construed. *See Markman v. Westview Instr., Inc.*, 517 U.S. 370, 374 (1996) ("Victory in an infringement suit requires a finding that the patent claim 'covers the alleged infringer's product or process'"). A patent holder's infringement accusation creates no presumption that the challenged product actually infringes. And while patent holders enjoy a statutory presumption of validity, that presumption is rebuttable and simply places the burden of persuasion on the party challenging validity. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007). In the pharmaceutical industry, alleged infringers frequently meet this burden, resulting in rulings that invalidate the patent.[17]

A patent holder seeking to exclude a rival prior to final adjudication of the patent dispute thus must obtain a preliminary injunction. The patentee cannot merely assert in good faith that

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[16] 35 U.S.C. § 154(a)(1) grants patentees "the right to exclude others from making, using, offering for sale, or selling the invention."

[17] *See, e.g., Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254 (Fed. Cir. 2007) (patent covering method of treating ear infections with ofloxacin held invalid); *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007) (patent covering high blood pressure drug Altace found invalid); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006) (patent claims related to extended release urinary incontinence drug Ditropan XL held invalid and not infringed).

the challenged product infringes, nor can it sit back and rely on the presumption of validity.[18] Instead, like other litigants, it must establish its right to relief by showing, among other things, a likelihood of success on the merits. *See, e.g., eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). Moreover, the Supreme Court's decision in *eBay* made it clear that even successful patentees do not have an absolute "right to exclude" demonstrated infringers. *Id.* at 392. Overturning the Federal Circuit, the Supreme Court explicitly rejected the argument that a patentee's "right to exclude" justifies injunctive relief for successful patent litigants in every case. *Id.* ("[T]he creation of a right is distinct from the provision of remedies for violations of that right.").[19] Rather, patentees must establish entitlement to a permanent injunction under the analysis generally applicable to equitable relief. *Id*. Cephalon attempts to brush aside *eBay* on the ground that it is "not an antitrust case or even a Hatch-Waxman case." (Def.'s Mem. 32.) But *eBay* plainly rejects the view that the patentee's right to exclude within the patent term is without limits, as Cephalon urges, as it unquestionably places conditions on the patentee's ability to obtain an injunction excluding an alleged infringer.

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[18] *See, e.g., Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1335 (Fed. Cir. 2006) (vacating grant of preliminary injunction and stating "'if [the alleged infringer] raises a substantial question concerning . . . validity, i.e. . . . [an] invalidity defense that the patentee cannot prove 'lacks substantial merit,' then the patentee has not established a likelihood of success on the merits") (citations omitted).

[19] *eBay* is just one recent example of the Supreme Court's rejection of Federal Circuit rulings that were based on an overly expansive concept of patent rights. *See also Quanta Computer, Inc. v. LG Elecs., Inc.*, 128 S. Ct. 2109 (2008) (rejecting Federal Circuit's holding that patent exhaustion did not apply to method patents); *KSR,* 550 U.S. at 398 (holding that Federal Circuit's test for invalidating patents on obviousness grounds was too rigid); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (finding that Federal Circuit's test for finding subject matter jurisdiction for declaratory judgment actions was too restrictive).

Treating a patentee's *unproven* "right to exclude" as an absolute entitlement to purchase a permanent injunction with monopoly profits is thus flatly inconsistent with these established Supreme Court principles. As the above cases make clear, the patent's potential power to exclude competitors is tempered by the risk that the patentee's arguments will not prevail in court. In pharmaceutical patent litigation, the risk that the patentee will fail in its attempt to exclude is substantial: the patentee loses in 70 percent of the cases, according to two studies.[20]

To be sure, the patentee can avoid the risk of losing its patent dispute by settling prior to judgment. In that context, the stronger the patentee's validity and infringement arguments, the more advantageous the terms it can negotiate.[21] When a patentee asserts its patent and threatens a lawsuit with the goal of excluding a competitor from the market, the strength of its patent may either convince the accused infringer to accede or convince a court to issue an injunction. In either case, the exclusion results from the strength of the patent.

According to the end-of-patent-term standard, however, a patentee with monopoly power need not rely on the strength of its patent to prevent competition. Rather, the standard permits the patentee to achieve what its patent alone cannot, by sharing its monopoly profits with its

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[20] (FAC ¶ 25); *see also* Paul Janicke & LiLan Ren, *Who Wins Patent Infringement Cases?* 34 AIPLA Q.J. 1, 20 (2006) (finding in an analysis of 2002-04 Federal Circuit decisions on the merits of pharmaceutical patent claims that alleged infringers succeeded in 70 percent of the cases); Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, 19-20 (July 2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>. (finding in an FTC study of all patent litigation initiated between 1992 and 2000 between brand drug manufacturers and Paragraph IV generic applicants that, when cases were litigated to a decision, generics prevailed in cases involving 73 percent of the challenged drug products).

[21] *See, e.g.,* Michael J. Meurer, *The Settlement of Patent Litigation,* 20 RAND J. ECON. 77, 77-79 (1989) (a patentee will often settle a dispute by licensing the patent in exchange for royalty payments to avoid the threat of having its patent invalidated; the terms of the license depend, in part, on the probability of the patentee's prevailing in litigation).

rivals. By permitting patentees to buy off competition until patent expiration, the end-of-patent-term standard grants trivial patents – those that are likely invalid or so narrow that infringing them can be easily avoided – the same exclusionary force as strong patents. Indeed, the incentive to pay a generic to abandon its patent challenge is likely to be greatest when the patent infringement claim is weak. *See, e.g., Tamoxifen*, 466 F.3d at 211.

Cephalon does not dispute that patent holders will most likely use exclusion payments to protect the weakest patents, if allowed to do so. According to Cephalon, granting patent holders this extraordinary right is necessary to further the patent system's goal of encouraging innovation. (Def.'s Mem. 13.) But as the Supreme Court stated in *KSR*, were the patent system to protect trivial inventions with exclusive rights, "patents might stifle, rather than promote, the progress of useful arts." 550 U.S. at 427. Indeed, "[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress" by preventing the public from using ideas that would otherwise be freely available. *Id.* at 419. *Cf. Abbott Labs.*, 432 F. Supp. 2d at 422 (Jordan. J.) (denying motion to dismiss despite objections that recognizing antitrust claim would harm pharmaceutical product innovation).

The Supreme Court has made clear that patent law must be construed and applied "to give effect to the public policy which limits the granted monopoly strictly to the terms of the statutory grant." *United States v. Univis Lens Co.*, 316 U.S. 241, 251 (1942). "It is the public interest which is dominant in the patent system." *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 665 (1944). For that reason, a long line of Supreme Court cases has held that a licensee may later attack the validity of the patent under which it was licensed.[22] In *Lear, Inc. v.*

[22] *See, e.g., MedImmune*, 549 U.S. at 118 (holding that licensee need not stop paying royalties to seek a declaratory judgment that patent is invalid, unenforceable, or not infringed).

Adkins, 395 U.S. 653, 670 (1969), the Court explained that this result is necessary to vindicate "the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain." Otherwise, "the public may continually be required to pay tribute to would-be monopolists without need or justification." *Id.*[23] In *United States v. United States Gypsum Co.*, 333 U.S. 364, 388 (1948), the Court applied the same principle to antitrust enforcement actions brought by the government, holding that when a defendant asserts a patent as a defense to antitrust liability, the government may challenge the patent's validity, to "show that the asserted shield of patentability does not exist." *See also United States v. Glaxo Group Ltd.*, 410 U.S. 52, 57 (1973) ("the United States is entitled to attack the validity of patents relied upon to justify anticompetitive conduct otherwise violative of the law").[24] The end-of-patent-term standard contradicts these Supreme Court cases.

As the leading antitrust treatise observes: "[Intellectual property] rights, like all property rights. . . do not include rights to violate the antitrust laws unless a more particularized warrant can be found in the IP statute or sound policy analysis." Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law*, ¶ 2046c at 444 (2007 Supp.). The end-of-patent-term standard – by allowing a patent holder to avoid scrutiny of a weak patent simply by agreeing to split monopoly profits with patent challengers – finds no support in the Supreme Court's patent law or policy.

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[23] *See also Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 349-50 (1971) (noting the Court's "consistent view" that a patentee "should not be insulated from the assertion of defenses and thus allowed to exact royalties for the use of an idea that is not in fact patentable or that is beyond the scope of the patent monopoly granted").

[24] Citing *Glaxo*, Cephalon claims that the government's authority to attack a patent's validity is limited to determining the remedy for an already established antitrust violation. (Def.'s Mem. 32.) But *Gypsum* demonstrates that this is not the case. 333 U.S. at 388.

B. The end-of-patent-term standard improperly gives private agreements the same antitrust protection afforded government petitioning

Prosecuting a patent infringement case normally does not implicate the antitrust laws, even though such a suit by its nature seeks to eliminate competition. The Supreme Court has held that the Sherman Act does not prohibit parties from petitioning the government for an anticompetitive result (*see E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961)), and that filing a lawsuit is petitioning. *See Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508 (1972). Consequently, absent a sham infringement claim or fraud, patent litigation enjoys antitrust immunity. *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993) (filing of non-sham lawsuit is protected from antitrust challenge); *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965) (fraud in procuring patent deprives patentee of immunity that normally protects bringing of an infringement action).

Of course, as discussed above, when patent holders choose this protected avenue of enforcement they face the risk that they cannot meet the high burden for obtaining a preliminary injunction or that their patent may ultimately be found invalid, not infringed, or unenforceable. Alternatively, they can avoid this risk by settling their infringement claim. Settlements are generally encouraged, as they save private and court resources. But private agreements that settle litigation do not enjoy the broad antitrust immunity afforded to petitioning the government through litigation. *See, e.g., Masonite*, 316 U.S. at 265. As one court explained in rejecting antitrust immunity for a private settlement agreement:

> When parties petition a Court for judicial action [*Noerr-Pennington*] protection attaches, but when they voluntarily withdraw their dispute from the court and resolve it by agreement among themselves there would be no purpose served by

> affording *Noerr-Pennington* protection. The parties by so doing must abide with any antitrust consequences that result from their settlement.

In re N.M. Natural Gas Antitrust Litig., MDL No. 403, 1982 WL 1827, at *6 (D.N.M. Jan. 26, 1982).[25] The patentee, therefore, may choose between litigation to enforce its patent – with antitrust immunity but the risk that the suit will be unsuccessful – and non-petitioning action through settlement, which avoids the risk of an adverse decision but offers no antitrust immunity.

The end-of-patent-term standard, however, inappropriately "treats a private settlement agreement excluding competition as the equivalent of a litigated judgment affirming the validity of the patent." DOJ *Cipro* Amicus Br., *supra* note 1, at 15. Applying a litigation immunity standard to such non-petitioning conduct enables patent holders to have it both ways: they can use collusive agreements to avoid the risk that patent litigation could lead to an unfavorable outcome, but still enjoy the protection from antitrust scrutiny afforded to enforcement through litigation. But as discussed above, the risk that a patent infringement claim will be unsuccessful is fundamental to the carefully-crafted balance that Congress struck in the Patent Act: "It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly." *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892). The end-of-patent term standard, which immunizes a settlement from antitrust scrutiny to the same degree as the filing of a lawsuit, is inconsistent with that balance.

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[25] *See also Andrx*, 256 F.3d at 799 (rejecting argument that settlements are *Noerr* protected); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 642 (E.D. Mich. 2000) (denying motion to dismiss because private settlement does not enjoy *Noerr* immunity); *In re Ciprofloxacin Hydrochloride Antitrust Litig.,* 261 F. Supp. 2d 188 (E.D.N.Y. 2003) (rejecting *Noerr* immunity for private settlement agreement entered by court as consent judgment).

Contrary to Cephalon's claim, the Supreme Court's decision in *Walker Process*, 382 U.S. at 172, does not support affording private settlement agreements in patent cases the same antitrust protection as government petitioning. (*See* Def.'s Mem. 32-33.) In *Walker Process*, the Supreme Court held that allegations of fraud in obtaining a patent may form the basis of an antitrust claim challenging otherwise protected patent litigation. 382 U.S. at 174. Such conduct is crucially different from Cephalon's conduct here. Antitrust challenges to exclusion payment settlements are not predicated on a patentee's unilateral effort to secure governmental action. Rather, they challenge collusive agreements in which previously adverse parties join forces to maintain the patentee's monopoly and share the benefits of avoiding competition. *See Singer*, 374 U.S. at 196-97 (antitrust law "imposes strict limitations on the concerted activities in which patent owners may lawfully engage"). Such activity raises antitrust risks not present when parties merely petition for governmental action. The end-of-patent-term standard, however, erroneously equates the two, a result not supported by *Walker Process* or any other Supreme Court decision.

C. The end-of-patent-term standard rests on flawed factual premises

In support of the end-of-patent-term standard, Cephalon argues that exclusion payments can virtually never be anticompetitive because: (1) they are a "natural consequence" of the Hatch-Waxman Act (Def.'s Mem. 16); and (2) it is "often impossible" to settle Hatch-Waxman patent litigation without such payments. (Def.'s Mem. 36). Both premises directly contradict the FTC's complaint, which tells a very different story about why Cephalon paid the generic companies in this case. And the reasoning of the courts that have adopted these premises is at odds with the reasoning of the Third Circuit in antitrust cases.

1. As the FTC alleges in its complaint, Cephalon's exclusion payments are not a natural consequence of the Hatch-Waxman Act

Cephalon asks this Court to believe that its payments to the first filers to forgo entry until 2012 are "merely a by-product of the incentives and risks created by Hatch-Waxman" (Def.'s Mem. 16), rather than a scheme to bolster a weak patent, as the complaint alleges. According to Cephalon, the pre-entry litigation that Hatch-Waxman encourages means that generic companies have dramatically increased leverage in settlement negotiations, because the branded-drug firm has no damage claim to use as a bargaining chip. (*Id.* at 17.) Consequently, Cephalon protests, "[t]here is . . . nothing anticompetitive about settlement payments to generics." (*Id*. at 18.)

Cephalon's argument contradicts the very thrust of the FTC's complaint, which alleges that in *this case*, Cephalon feared generic entry and used its monopoly profits to obtain protection from competition that its particle-size patent would not provide. Indeed, the complaint specifically alleges that Cephalon had to pay the generic firms as part of its settlements because Cephalon's patent was weak – not because of the Hatch-Waxman Act. (FAC ¶¶ 35-37, 41-45, 46-52, 55.) On a motion to dismiss, Cephalon may not dispute these allegations by offering its own explanation for its payments.[26]

Indeed, Cephalon's suggestion that this Court must reject, as a matter of law, the FTC's factual allegations that Cephalon's payments were designed to, and did, delay generic entry conflicts with the Third Circuit's decision in *Broadcom*, 501 F.3d at 297. In that case, the district court granted Qualcomm's motion to dismiss allegations of abuse of a standard-setting

[26] *See In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 398 (3d Cir. 2000) (stating that district court may not take judicial notice of "facts gleaned from counsel's argument"); Fed. R. Evid. 201(b) (a fact subject to judicial notice is "one not subject to reasonable dispute in that it is either (1) generally known … or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned").

process. The court reasoned that Qualcomm's patent rights conferred a "legally-sanctioned monopoly" and that the absence of competition "was the inevitable result of any standard-setting process," not the result of Qualcomm's conduct, as the complaint alleged. *Id.* at 305. The Third Circuit reversed, stating that "the [district court] erroneously assumed that monopoly is the 'natural consequence of the standard-setting process,' an unsupported factual finding that ignores the possibility of a standard comprised of nonproprietary technologies." *Id.* at 317.[27] Cephalon asks this Court to make the same type of "erroneous assumption" when it insists that its payments to its generic rivals are the natural consequence of the Hatch-Waxman Act. But as one of the Act's co-authors has observed, payments to keep generics out of the market have "turned the policies of the [Act] on their head" by undermining its goal of getting generics to the market more quickly.[28]

Moreover, the reasoning underlying the "natural consequences" argument conflicts with Third Circuit antitrust analysis in *LePage's* and *Dentsply*. Cephalon makes much of a supposed "asymmetry of risk" between brand and generic firms based on the substantial differential between the profits the brand stands to lose and profits the generic stands to gain. (*See* Def.'s Mem. 17-18, 35-36.) But any monopolist – with or without a patent – has the incentive to protect its monopoly profits when faced with a competitive threat. As the Third Circuit stated in *LePage's*, 324 F.3d at 163, "a defendant's assertion that it acted in furtherance of its economic

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[27] *See also Glaberson v. Comcast Corp.*, No. 03-6604, 2006 WL 2559479 (E.D. Pa. Aug. 31, 2006) (denying motion to dismiss antitrust claims over defendant's objection that conduct was sanctioned by applicable regulatory scheme).

[28] Motion and Brief of Representative Henry A. Waxman as *Amicus Curiae* in Support of Petitioner at 1, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273) ("Waxman Amicus Br."), *available at* <http://www.citizen.org/documents/waxmanamicus.pdf>.

interests does not constitute the type of business justification that is an acceptable defense to . . . monopolization." The Third Circuit reiterated this principle in *Dentsply*, 399 F.3d at 191, when it held that Dentsply's exclusionary agreements with dealers were unlawful, even though "[t]he results have been favorable to Dentsply." Cephalon's argument that it had much to lose in the patent litigation, and thus was justified in making "natural" exclusion payments to risk-seeking generics, is flatly inconsistent with the analysis in these Third Circuit cases.

In the end, Cephalon's "natural consequences" argument relies entirely on acceptance of this supposed fact by other courts of appeals. But, as noted above, the reasoning of these other courts conflicts with Third Circuit jurisprudence. And, while Cephalon claims that this Court may simply reject on a motion to dismiss the FTC's factual allegations that Cephalon paid its generic rivals to delay entry, the cases it cites do not support its position *See, e.g., Democratic Party of U.S. v. Nat'l Conservative Political Action Comm.*, 578 F. Supp. 797, 803 (E.D. Pa. 1983) (decision after evidentiary hearing; motion to dismiss previously denied); *Schering-Plough Corp., v. FTC*, 402 F.3d 1056, 1071 (11th Cir. 2005) (decision on full administrative record); *Cipro*, 544 F.3d at 1326 (decision on summary judgment record). Only the *Tamoxifen* court accepted a Hatch-Waxman by-product argument on a motion to dismiss. 466 F.3d at 206-08. But while this Court may take judicial notice of the existence of another court's opinion, it may not do so "for the truth of the facts recited therein." *Southern Cross Overseas Agencies*, 181 F.3d at 426; *see also In re Wellbutrin SR Antitrust Litig.*, Nos. 04-5525, 04-5898, 05-396, 2006 WL 616292, at *6 (E.D. Pa. March 9, 2006) (court may not "make factual findings in this case based on the facts recited in the opinions of other courts.").

2. As the FTC alleges in its complaint, exclusion payments are not necessary to settle Hatch-Waxman patent litigation

Cephalon's argument starts with an unobjectionable proposition: courts should generally promote settlement of litigation. (Def.'s Mem. 13.) From there, however, Cephalon goes on to suggest that alleged generic infringers are overly optimistic in their view of the patent litigation merits; that because of this over-optimism, settlement of Hatch-Waxman litigation is "often impossible" without exclusion payments; and that subjecting such payments to antitrust scrutiny is therefore bad policy. (*Id.* at 36.) Cephalon's underlying factual premises not only contradict the allegations of the complaint, they are wrong. And its legal conclusion is undermined by Third Circuit precedent.

The complaint alleges that generic companies, Cephalon, and independent observers knew that Cephalon's particle-size patent was unlikely to prevent generic competition. (FAC ¶¶ 45-51.) Those allegations contradict Cephalon's suggestion that the generic challengers were overly optimistic. The complaint also alleges that "pharmaceutical patent litigation can be, and often is, resolved without exclusion payments from branded companies to generic companies." (¶ 98.) And the complaint specifically alleges that it was possible that "Cephalon would have agreed to settle its patent litigation on terms that did not compensate the First Filers, but instead provided for generic entry earlier than 2012." (¶ 85.) Cephalon essentially argues that the complaint is wrong, but on a motion to dismiss, the complaint's allegations and all reasonable inferences must be accepted.

The specific complaint allegations in this case are consistent with the observed ability generally of branded pharmaceutical companies to settle patent litigation without paying the alleged generic infringer. Beginning in 2000, the FTC brought several enforcement actions

challenging exclusion payments in Hatch-Waxman patent litigation and until 2005,[29] these enforcement actions appear to have deterred exclusion payments. During this time, parties nonetheless routinely settled Hatch-Waxman patent cases – they simply did so without payments.[30] This history suggests that Cephalon's argument – that a judicial rule subjecting exclusion payment settlements to antitrust scrutiny will make it impossible to settle many cases – is unlikely to be borne out by the facts. In any event, it contradicts the complaint. (¶ 98.)

Moreover, even if imposing some antitrust limit on the way parties choose to settle were to result in fewer settlements, that would hardly justify a rule blessing anticompetitive settlements. *See, e.g., Singer*, 374 U.S. at 196-97. The Third Circuit considered a similar argument in *Mannington Mills,* 610 F.2d at 1059. In that case, defendant had argued "that overly restrictive antitrust review of patentee licensing practices might lead a patentee to license less widely than he might otherwise do, or indeed, not to license at all." *Id.* at 1071. But the Third Circuit reversed the district court's grant of summary judgment to the defendant, concluding that the risks to antitrust policy weighed against the district court's overly permissive treatment of patent licenses because "restrictive [patent] licensing practices may have significant anticompetitive effects." *Id.* Here the FTC has specifically alleged that Cephalon's exclusion payment settlements have had significant anticompetitive effects – costing consumers of hundreds of millions of dollars a year – that far outweigh any cost-savings resulting from Cephalon's settlements.

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[29] In 2005, the Eleventh Circuit issued the *Schering* decision and shortly thereafter, the Second Circuit issued the *Tamoxifen* decision.

[30] For example, in fiscal year 2004, 14 pharmaceutical patent settlements were filed with the FTC under the Medicare Modernization Act and none involved both a payment from the brand to the generic and an agreement to defer generic entry. (FAC ¶ 98.)

III. This Court Should Not Follow Decisions From Other Jurisdictions That Have Adopted Cephalon's End-of-Patent-Term Standard

Cephalon urges this Court to adopt its end-of-patent-term standard, which it claims is the "prevailing legal standard." (Def.'s Mem. 29.) But, as discussed above, that standard grants more protection than patent law or patent policy provide. Moreover, Cephalon errs when it claims that the Third Circuit owes any deference to the Federal Circuit's decision in *Cipro*. Furthermore, as discussed below, other courts have refused to adopt this extreme view which has been widely criticized on legal and policy grounds.[31] This Court should do the same and decline to follow the Second and Federal Circuit's approach, both on the law and on the facts of this case. *See Carpenter Tech. Corp. v. Allegheny Techs., Inc.*, No 08-2907, 2009 WL 2170111, at *7 n.9 (E.D. Pa. July 16, 2009) (denying motion to dismiss antitrust claim, and noting that defendant relied on Seventh Circuit law, which is not controlling authority).

A. The Third Circuit owes no deference to the Federal Circuit's *Cipro* decision

Third Circuit law controls this case. Cephalon makes a half-hearted attempt in a footnote to dispute this proposition, suggesting that the Federal Circuit "likely" has jurisdiction over any appeal in this case. (Def.'s Mem. 20 n.12.) But as its placement reflects, this suggestion has no merit. The Second Circuit has twice rejected defense arguments that the Federal Circuit has exclusive jurisdiction over antitrust challenges to exclusion payment settlements.[32] As in those

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[31] *See also Newmark v. Principi*, 283 F.3d 172, 174 (3d Cir. 2002) ("[D]ecisions made in other jurisdictions are not binding on us, we will examine and interpret [the law] in the light of our precedent").

[32] Order Denying Motion to Transfer Appeals Nos. 05-2851, 05-2582, and Granting Motion to Transfer Appeal No. 05-2863, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, Nos. 05-2851, 05-2852, 05-2863 (2d Cir. Nov. 7, 2007) (denying motion to transfer two appeals to the Federal Circuit "because the claims therein rely on several theories, including alternative theories that do not require the determination of any substantial questions of patent law.")

cases, the FTC has challenged payments not to compete, and Cephalon has raised a claim of patent immunity as a defense. But as the Supreme Court made clear in *Christianson*, 486 U.S. at 809, raising federal patent law as a defense does not create Federal Circuit jurisdiction, "even if the defense is anticipated in the complaint."[33]

Cephalon therefore resorts to a policy argument: that the Third Circuit should defer to the Federal Circuit's *Cipro* decision "in the interests of patent law uniformity." (Def.'s Mem. 19.) But this contention is equally misplaced. Under Cephalon's policy argument, in any case raising a patent defense, a court should ignore its own circuit antitrust law and instead adhere to Federal Circuit decisions. But, we know of no instance (and Cephalon cites none) of any regional circuit court accepting this proposition. Indeed, aside from cases involving matters of substantive patent law raised as counterclaims, we know of no instance of a regional circuit court finding that a Federal Circuit decision is entitled to greater deference than a decision from the appellate court in another circuit. Such decisions are simply entitled to whatever weight their persuasive value warrants. *See, e.g.*, *Telecom Technical Servs., Inc. v. Rolm Co.*, 388 F.3d 820, 826 (11th Cir. 2004) (observing that a recent Federal Circuit ruling in an antitrust case "only has

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("*Cipro* Transfer Order"); *Tamoxifen*, 466 F.3d at 199-200 (plaintiffs' challenge to exclusion payment settlement did not turn on a substantial question of federal patent law because there are "reasons completely unrelated to the provisions and purposes of federal patent law why the plaintiff may or may not be entitled to the relief it seeks" (quoting *Christianson v. Colt Indus. Operating Corp.,* 486 U.S. 800, 812 (1988))).

[33] The Federal Circuit's jurisdiction extends only to cases "arising under" a federal patent statute. 28 U.S.C. §§ 1295(a)(1), 1338(a). A case "arises under" federal patent law only if "a well-pleaded complaint establishes that either federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law." *Christianson*, 486 U.S. at 809.

persuasive authority"). None of the cases Cephalon cites supports a contrary conclusion.[34] And, none of the regional circuit courts that have addressed antitrust claims challenging exclusion payment patent settlements have suggested that matters of patent law uniformity were at stake. *See Tamoxifen*, 466 F.3d at 187; *Schering*, 402 F.3d at 1056; *Cardizem*, 332 F.3d at 896. Accordingly, this Court can and should decline to follow the Federal Circuit's erroneous *Cipro* decision.

B. Other courts have not adopted the end-of-patent-term standard

As detailed in Section I above, a number of courts that have considered antitrust challenges to pharmaceutical exclusion payments have found that they can be anticompetitive, rejecting the end-of-patent-term standard. *See Cardizem*, 332 F.3d at 896 (affirming summary judgment ruling of illegality); *Andrx*, 256 F.3d at 799 (reversing grant of motion to dismiss); *Terazosin*, 352 F. Supp. 2d at 1279 (on summary judgment, holding agreement illegal); *K-Dur*, 338 F. Supp. 2d at 517 (denying motion to dismiss).

Cephalon tries to distinguish *Cardizem, Andrx,* and *Terazosin* because they involved "interim" agreements, in which the generic firms agreed not to compete only during the pendency of the patent litigation. But where the patent holder pays the alleged infringer – whether in the context of an interim or final agreement – the core concern is the same: that the

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[34] The only regional circuit court case Cephalon cites, *Schinzing v. Mid-States Stainless, Inc.*, 415 F.3d 807 (8th Cir. 2005), is merely an example of a court choosing to apply Federal Circuit precedent to resolve a counterclaim of patent invalidity. Moreover, the Federal Circuit "patent immunity" cases it cites – *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.,* 375 F.3d 1341 (Fed. Cir. 2004), and *Nobelpharma AB v. Implant Innovations, Inc.,* 141 F.3d 1059 (Fed. Cir. 1998), involved antitrust claims that fall within that circuit's exclusive jurisdiction and reflect the Federal Circuit's choice of law analysis. The same is true of *In re Wellbutrin SR Antitrust Litig.*, 2006 WL 616292 at *1 (antitrust case predicated on claims that patentee engaged in sham litigation).

patent holder has not merely "take[n] advantage" of its patent monopoly, but rather "bolster[ed] the patent's effectiveness" with payments. *Cardizem*, 332 F.3d at 908. Moreover, the differences between final settlements with payments and interim agreements with payments hardly suggest that one involves the legitimate exercise of patent rights and the other does not, as Cephalon implies. Indeed, if a final settlement with a payment to eliminate competition for the entire life of the patent is within the scope of the patent grant, then an interim agreement that eliminates competition only during the pendency of the litigation logically must be within the scope of the grant as well. But *Cardizem, Andrx,* and *Terazosin* all reject the premise that use of exclusion payments in an interim agreement is merely the legitimate exercise of patent rights.

Further, Cephalon's assertions concerning Eleventh Circuit precedent are overstated because that Circuit's rulings are not squarely aligned with Second and Federal Circuit holdings adopting the end-of-patent-term standard. To be sure, when the FTC asked the Supreme Court to review the *Schering* decision (and when advocating legislation before Congress), it expressed concern that the Eleventh Circuit adopted an overly lenient standard. But the Eleventh Circuit decisions are not without ambiguity. Indeed, each appears to suggest that the appropriate analysis of an exclusion payment settlement may involve some assessment of the strength of the underlying patent, an inquiry the end-of-patent-term standard expressly forecloses.

In *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), the Eleventh Circuit rejected plaintiff's contention that the challenged agreements were *per se* unlawful "merely because" of a subsequent finding of patent invalidity, (*Id.* at 1308), and remanded the case for consideration of the "protection afforded by the patents" based on "the likelihood of [the patentee] obtaining such protections" at the time of the agreements. *Id.* at

1306, 1312.[35] On remand, the district court considered the strength of the patent holder's claims, concluded that the patentee was not likely to have obtained through litigation the protection that the exclusion payments bought, and, thus held that paying a generic to stay off the market was an illegal restraint of trade. *Terazosin*, 352 F. Supp. 2d at 1319.[36]

In *Schering*, the Eleventh Circuit reaffirmed its holding in *Valley Drug,* stating that the antitrust analysis of a patent settlement must determine the extent to which the challenged agreement exceeds "the scope of the exclusionary potential of the patent." 402 F.3d at 1066. The court stressed the "need to evaluate the strength of the patent" (*id.* at 1076), and faulted the FTC for not doing so.[37] Finally, in *Andrx Pharmaceuticals, Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005), the Eleventh Circuit allowed an antitrust challenge to a pharmaceutical exclusion payment settlement to go forward, reversing the district court's grant of judgment on the pleadings. In so doing, the court suggested that the scope of the patent's exclusionary

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[35] Cephalon incorrectly suggests that *Valley Drug* remanded only the interim agreement. In *Valley Drug*, the court considered two agreements: (1) an interim settlement between Abbott and Geneva; and (2) a final settlement between Abbott and Zenith. The Eleventh Circuit remanded both "Agreements" to the district court. *See, e.g., id.* at 1312 (instructing the district court to identify "the protection afforded by the patents and the relevant law and consideration of the extent to which the ***Agreements*** reflect a reasonable implementation of these") (emphasis added); *Id.* at 1313 (on remand, district court should consider whether "part, but not all, of the provisions of the ***Agreements*** violate the Sherman Act") (emphasis added).

[36] *See also Kaiser Found. Health Plan Inc. v. Abbott Labs., Inc.* 552 F.3d 1033, 1041 (9th Cir. 2009) (explaining that, in *Valley Drug*, the Eleventh Circuit indicated "that the district court might be able to find a per se violation [of Section 1 of the Sherman Act] if it reframed its analysis.")

[37] The FTC had held that the best indication of patent strength was the inclusion of substantial payments in the settlements, and declined to directly assess the merits of the patent case. The Eleventh Circuit's disagreement with this approach does not mean it necessarily adopted the end-of-patent-term standard.

potential should be assessed in light of whether the relevant patent is "necessary" to the manufacture and sale of a generic product. *Id.* at 1235.

Others have noted that the Eleventh Circuit has not expressly foreclosed an inquiry into the strength of the patent. For example, the Solicitor General observed in 2006 that "[n]either *Valley Drug* nor [*Schering*] holds . . . that evidence of invalidity or non-infringement available at the time of the settlement would be irrelevant in assessing the permissibility of a reverse payment."[38] Fifty-four legal scholars and other academics describe the Eleventh Circuit as applying "its own modified version of the rule of reason that inquires into the underlying validity of the patent before characterizing the conduct."[39] And the respondents in the *Schering* case told the Supreme Court that the Eleventh Circuit's decision permits an inquiry into the "the strength of Schering's patent case."[40]

C. The end-of-patent-term standard has been widely criticized on legal and policy grounds

The sweeping immunity standard articulated in the *Tamoxifen* and *Cipro* decisions has been widely criticized on legal and policy grounds. The Solicitor General, in a 2007 amicus brief to the Supreme Court, called the standard set forth in *Tamoxifen* "erroneous," an

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[38] Brief for the United States as Amicus Curiae at 17-18, *FTC v. Schering-Plough*, 548 U.S. 919 (2006) (cert. denied) (No. 05-273).

[39] Brief Amici Curiae of 54 Intellectual Property Law, Antitrust Law, Economics and Business Professors, the American Antitrust Institute, the Public Patent Foundation, and the AARP in Support of the Petitioner at 4, *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 129 S. Ct. 2828 (2009) (No. 08-1194) (cert. denied) ("Academic *Cipro* Amicus Br.").

[40] Brief in Opposition at 23, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273) (cert. denied) (stating that the Court of Appeals decision "accommodates" the goals of Hatch Waxman because it permits a judgment about the exclusionary potential of Schering's patent based on the evidence adduced at trial concerning the strength of Schering's patent case).

"insufficiently stringent standard for scrutinizing patent settlements," and one that gives "undue weight" to the general public policy encouraging settlement at the expense of the public interests at stake in this case.[41] As the Solicitor General observed, "the interests in consumer welfare protected by the antitrust laws militate against adoption of a legal standard that would facilitate a patent holder's efforts to preserve a *weak* patent by dividing its monopoly profits with an alleged infringer." U.S. *Tamoxifen* Amicus Br., *supra* note 41, at 11 (emphasis in original); *see also* *Tamoxifen*, 466 F.3d at 228 (Pooler, J., dissenting) ("[T]he majority's requirement that an antitrust plaintiff show that a Hatch-Waxman lawsuit settled by agreement was a sham . . . is unjustified. A more searching inquiry and a less stringent standard are required to properly protect all interests.").

Currently, the Second Circuit is revisiting the rule the divided panel adopted in *Tamoxifen.* The court is considering an appeal of antitrust cases involving the same exclusion payment settlement that was upheld by the Federal Circuit in *Cipro*.[42] Despite its own *Tamoxifen* precedent, the Second Circuit invited the Department of Justice to address the legality of a brand paying its potential generic rival to abandon its patent challenge and refrain from competing. In response, the Department of Justice reiterated its criticism of the *Tamoxifen* standard and offered a different approach, stating that "[t]he anticompetitive potential of reverse payments in the Hatch-Waxman context in exchange for the alleged infringer's agreement not to

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[41] Brief for the United States as Amicus Curiae at 12-14, *Joblove v. Barr Labs. Inc.*, 551 U.S. 1144 (2007) (No. 06-830) ("U.S. Tamoxifen Amicus Br.").

[42] The Second Circuit transferred one of the *Cipro* cases to the Federal Circuit because, unlike the cases it retained, the complaint included a claim that falls with the exclusive jurisdiction of the Federal Circuit. *Cipro* Transfer Order, *supra* note 32.

compete . . . is sufficiently clear that such agreements should be treated as presumptively unlawful under Section 1 of the Sherman Act."[43]

The permissive treatment of exclusion payment agreements by some appellate courts has also prompted numerous others to point out the flaws in those decisions. Fifty-four legal scholars, economics professors, and other academics criticized the Federal Circuit's *Cipro* opinion as "far outside the mainstream of judicial and academic analysis" and containing "fundamental errors of economic reasoning."[44] The American Medical Association and consumer groups, such as AARP and Consumers Union, have expressed concerns that exclusion payment settlements "create barriers to affordable prescription drugs and impose substantial costs on the health care system as a whole,"[45] and that courts have blessed "patently anticompetitive settlements."[46] And as Representative Henry A. Waxman, co-author of the Hatch-Waxman Act has observed, the lenient approach to exclusion payment agreements has "turned the policies of the [Act] on their head." Waxman Amicus Br., *supra* note 28, at 1. The Hatch-Waxman Act was intended to facilitate elimination of unjustified patent barriers and thereby speed consumers' access to low-cost generic drugs – not to facilitate anticompetitive agreements, as the end-of-patent-term standard would do. *Id.* at 1, 11.

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[43] DOJ *Cipro* Amicus Br., *supra* note 1, at 10. *See also id.* at 15 ("The Tamoxifen standard . . . upsets the carefully crafted balance that Congress struck in the Patent Act.").

[44] Academic *Cipro* Amicus Br., *supra* note 39, at 2, 4.

[45] *See* Statement of the American Medical Association to the Subcommittee on Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce, *Impact of "Pay-for-Delay" Settlements On Patient Access to Affordable Generics and Overall Health Care System Costs*" (Apr. 13, 2009) at 1.

[46] Letter to Eric H. Holder, Jr., Attorney General, from AARP, et al. (April 17, 2009) at 4.

D. The facts in this case illustrate why this Court should not adopt the end-of-patent term approach taken in *Tamoxifen* and *Cipro*

The *Tamoxifen* majority acknowledged that a rule protecting settlements in which branded and generic rivals agree to avoid competition and share the resulting profits would protect patents that are "fatally weak." *Tamoxifen*, 466 F.3d at 212. Indeed, *Tamoxifen* agreed with the district court's observation in *Cipro* that "'the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity.'" *Id*. at 211 (quoting *Cipro,* 363 F. Supp. 2d 514, 534 (E.D.N.Y. 2005). But the Second Circuit dismissed this concern in the belief that such settlements could not be an effective strategy to protect weak patents. In the court's view, other challengers would come forward and it would be too expensive to pay them off. The facts alleged in this case, however, show that the court's optimism was misplaced.

First, the Second Circuit assumed that it was not "realistic" to think that the brand drug firm could pay off multiple generic challengers:

> There is, of course, the possibility that the patent holder will continue to buy out potential competition such that a settlement with one generic manufacturer protecting the patent holder's ill-gotten patent monopoly will be followed by other settlements with other generic manufacturers should a second, third, and fourth rise to challenge the patent. We doubt however, that this scenario is realistic.

Tamoxifen, 466 F.3d at 211-12. But it surely is realistic: that is precisely what happened here. When multiple generic applicants seek to compete, the prospective profits of each will be substantially lower, since they do not enjoy any guaranteed exclusivity period. Consequently, the amount needed to buy off each subsequent potential competitor is far less. Cephalon had a weak patent – one that was narrow and of doubtful validity (FAC ¶¶ 41-45) – but it could and

did pay off four generic rivals to ensure that they would not enter the market, which they were otherwise likely to do. (¶¶ 2-3.)

Second, the *Tamoxifen* court assumed that paying a generic rival to drop its patent challenge "would have no effect on other challengers of the patent." *Tamoxifen*, 466 F.3d at 211. But while the regulatory interpretation in effect at the time of the *Tamoxifen* and *Cipro* settlements led to loss of 180-day exclusivity upon settlement, that is no longer the case.[47] Cephalon's settlements with the four first filers secured a 180-day exclusivity barrier that has kept subsequent generic challengers from competing with generic Provigil products, without regard to whether they infringe Cephalon's patent. (¶¶ 85-87.)

Finally, the *Tamoxifen* majority believed that settling with the first generic applicant would increase incentives for other generic firms to mount a challenge. *Tamoxifen*, 466 F.3d at 211. But this erroneous belief rested on an assumption that the 180-day exclusivity period awarded to first filers would be passed along to the next generic challenger in line.[48] That has never been the law. Even if a later challenger to Cephalon's particle size patent obtained a favorable court judgment that the patent is invalid or not infringed, it would not get FDA approval to sell its product until the first filers' exclusivity either expires or is forfeited. (FAC

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[47] *Tamoxifen*, 466 F.3d at 214 ("under procedures in effect at the time [of settlement]," the agreement between Zeneca, the branded drug firm, and Barr, the first generic filer, "appeared to ensure . . . that [Barr] was not eligible for the [180-day] exclusivity period."); *see Cipro*, 261 F. Supp. 2d at 243 ("the Settlement Agreements here did not make a 'bottleneck' for future ANDA IV filers"); *see also* 21 C.F.R. § 314.107(c)(1) (1997), *revoked*, Effective Date of Approval of Abbreviated New Drug Application, 63 Fed. Reg. 59710 (Nov. 5, 1998).

[48] *Tamoxifen*, 466 F.3d at 214 (stating incorrectly that the settlement between Zeneca and Barr meant other potential generic manufacturers would be "spurred by the additional incentive (at the time) of potentially securing the 180-day exclusivity period available upon a victory in a subsequent infringement lawsuit").

¶¶ 87-91.) Moreover, as the complaint alleges, the agreements here reduced the incentive to challenge Cephalon's patent because they include a "most favored nation" clause that allows for immediate entry by each settling first filer in the event that another generic company enters the market. (¶ 60.)

Thus, the facts of this case demonstrate that the anticompetitive implications the *Tamoxifen* court thought unrealistic are all too real. The complaint allegations here call into question the reasoning of the Second Circuit's *Tamoxifen* decision. Accordingly, this Court should decline to follow the same approach.

IV. The Court Does Not Face a Choice Among Types of Proof on a Motion to Dismiss

Cephalon attempts to justify the extreme standard it advocates by claiming that any other approach is "fundamentally flawed and completely unworkable." (Def.'s Mem. 34-41.)[49] The purported "flaws in theory" it points to, however, are either mischaracterizations of the complaint or a rehash of earlier claims about the "natural consequences" of the Hatch-Waxman Act and the difficulty of settling Hatch-Waxman patent litigation without payments.[50] As we explained in Section II.C, these assertions contradict the complaint and are inconsistent with the reasoning applied by the Third Circuit in antitrust cases. Cephalon's second objection – that any

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[49] Cephalon also asserts at the outset of its argument that the FTC's amended complaint advances "inconsistent alternative standards" (Def.'s Mem. 34), but never identifies the purported inconsistency.

[50] Cephalon wrongly asserts that the FTC alleges that the settlements are beyond the exclusionary power of the patent "merely because the parties could have theoretically agreed on an earlier entry date." (Def.'s Mem. 34.) Rather, as discussed above, the FTC alleges, based on numerous facts, that generic competition to Provigil would, in fact, have occurred prior to April 2012 absent Cephalon's payments to the first filers.

approach other than the one it prefers is "impractical" – is not only entirely misplaced on a motion to dismiss but also unfounded in fact.

The FTC's complaint alleges legally cognizable monopolization claims: that Cephalon has a monopoly and that it maintained its monopoly through a course of exclusionary conduct, including using its monopoly profits to purchase protection from competition that its patent did not afford.[51] There are various types of evidence that could be used to prove these allegations of exclusionary conduct, and the complaint includes a variety of supporting facts. But the proper approach to matters of proof (such as the type and quantity of evidence required) is not at issue at this juncture. As the Supreme Court made clear in *Twombly*, 550 U.S. at 556, "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts alleged is improbable and that a recovery is very remote and unlikely." *See also Fowler v. UPMC Shadyside*, No. 07-4285, 2009 WL 2501662, at *7 (3d Cir. Aug. 18, 2009) ("It is axiomatic that the standards for dismissing claims under Fed. R. Civ. P. 12(b)(6) and granting judgment under either Fed. R. Civ. P. 50 or Fed. R. Civ. P. 56 are vastly different").

Moreover, Cephalon's insistence that any approach other than the end-of-patent-term rule would be impossible to implement in practice is without merit.[52] Even the most exacting

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[51] Cephalon is wrong to suggest that the FTC claims that all payments from a brand company to generic patent challengers "must be" condemned as anticompetitive. (Def's Mem 34-35.) Rather, as noted above, such payments should be presumptively anticompetitive. But a defendant might rebut that presumption of illegality (as antitrust defendants may do in other contexts) by showing, for example, that the payment was for something other than avoidance of competition, such as saved litigation expenses.

[52] Commentators have proposed a variety of workable approaches. *See, e.g.*, Herbert Hovenkamp et al., *The Interface Between Intellectual Property Law and Antitrust Law*, 87 Minn. L. Rev. 1719, 1759 (2003) (payment from a patentee to an infringement defendant for the latter's exit from the market is presumptively unlawful); Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A*

approach, one that would require a direct assessment of the likely outcome of the patent suit (judged as of the time of the settlement) – a type of proof we believe is unnecessary here – could be implemented if the Court believes it is warranted. The district court's decision on remand in the *Terazosin* case demonstrates that such an inquiry can be practically undertaken. *See* 352 F. Supp. 2d at 1299-1308.

Cephalon's preferred legal rule may be simple to apply, but ease of application cannot justify an erroneous and extreme standard that misconstrues the nature of patent rights and inappropriately diminishes fundamental antitrust principles.

Commentary on Hovenkamp, Janis, and Lemley, 87 Minn. L. Rev. 1789, 1795-97 (2003) (burden on defendant to show likelihood of success in patent case); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L. Rev. 747, 750 (2002) (exclusion payments should be permitted unless plaintiff shows patentee's infringement suit unlikely to succeed).

CONCLUSION

Advances in the pharmaceutical industry bring enormous benefits. The development of new drugs is risky and costly, and preserving incentives to undertake this task is critically important. Due regard for patent rights is thus a fundamental premise of the Hatch-Waxman Act framework. But shielding exclusion payment settlements by drug companies from antitrust scrutiny would grant monopolists the ability to buy more protection from competition than their Congressionally-granted patent rights provide and would retard – rather than foster – innovation. Drug companies, like Cephalon, will use this power not to preserve legitimate patent monopolies, but rather to extinguish challenges to the weakest patents. As a result, consumers will lose billions of dollars in savings from low-cost generic drugs.

The Court should deny Cephalon's motion to dismiss.

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Respectfully submitted,

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